K071617

OCT 19 2007

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR.807.92.

9.1 SUBMITTER INFORMATION

a. Submitter Name:	Oral BioTech Inc.
b. Submitter Address:	812 Water St. NE Albany OR 97321
c. Submitter Telephone:	(541)928-4445
d. Submitter Facsimile:	(541)928-2444
e. Contact Person:	Bob Bowers Chief Operating Officer
f. Date Summary Prepared:	May 31, 2007

9.2 DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Oral Neutralizer
b. Classification Name:	Dental: Saliva, Artificial Unclassified

9.3 IDENTIFICATION OF PREDICATE DEVICES

The Oral Neutralizer by Oral BioTech is substantially equivalent to:

Laclede, Inc:	Oral Balance Gel and Liquid in K061331
Inpharma AB:	Caphasol in K991938
Gebauer Company:	Salivart in K981693
Sinclair Pharmacuticals	Salinum or Oraclair in K024148
Laboratories Carilene S.A.S	TGO Spray in K051812

9.4 DEVICE DESCRIPTION

Oral Neutralizer, like the mentioned pre existing devices, is an artificial saliva substitute which, like natural saliva, contains lubricating, neutralizing, and moistening properties to help alleviate the symptoms of dry mouth (xerostomia).

9.5 SUBSTANTIAL EQUIVALENCE/TECHNOLOGICAL CHARACTERISTICS

Summary of technological characteristics of the device as compared to the predicate devices:

Product	Oral Neutralizer	Oral Balance	TGO Spray	Caphesol	Salivart	Salinum/Oraclair
Intended Use	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia
Method of Use	Ready to use liquid, gel, spray	Ready to use Liquid and gel	Ready to use spray	Mix parts A&B ampoules	Ready to use spray	Ready to use liquid/rinse
Applications per Day	As needed	As needed	As needed	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
Type of product	Gel, solution	Gel, solution	solution	solution	solution	solution
Presentation	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile

9.6 INDICATIONS FOR USE

A refreshing gel, liquid, or spray that diminishes dry oral discomfort, neutralizes mouth odors, neutralizes and moisturizes oral biofilm, and other symptoms of a chronic or temporary dry mouth/xerostomia as a result of disease such as Sjogren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stress, or aging.

9.7 TESTS AND CONCLUSIONS

Functional and performance evaluation has been conducted to assess the safety and effectiveness of Oral Neutralizer liquid, gel, and spray. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2007

Mr. Robert Bowers
Chief Operating Officer
Oral BioTech, Incorporated
812 Water Street, North East
Albany, Oregon 97321

Re: K071617
Trade/Device Name: Oral Neutralizer
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LFD
Dated: August 22, 2007
Received: September 7, 2007

Dear Mr. Bowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

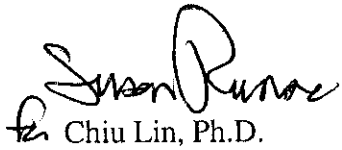
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K071617

Device Name Oral Neutralizer

Indications for use:

A refreshing gel, liquid, or spray that diminishes dry oral discomfort, neutralizes mouth odors, neutralizes and moisturizes oral biofilm, and other symptoms of a chronic or temporary dry mouth/xerostomia as a result of disease such as Sjogren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stress, or aging.

Do not write below this line - Continue on another page if needed

Prescription Use ___ OR Over the counter _X_
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071617